

All patients were successfully treated on the LM (stent length 15.7 ± 5.2 mm) and a final kissing balloon inflation was performed in 90%. Apart from the LM stenosis, a total of 1.2 ± 0.8 lesions were treated during the hospitalisation (total stent length 47 ± 16 mm). An intra-aortic balloon pump was used prophylactically in 1.3% and glycoprotein IIb/IIIa inhibitors in 10.8%. Transradial approach was used in 22% of the cases. In-hospital MACCE rate was 4.5% with 2.6% of mortality; at 9-month follow-up (FU), the global rate of event-free survival was 93.5% with a very low angiographic restenosis rate of 3%. Between 9 and 36-month clinical FU, there were one sudden death, 6 extra-cardiac deaths (total mortality 7%), one recurrent angina and 1 cardiac failure. Event free survival was 84%.

Conclusion: LM PCI using the TAXUS stent is feasible and safe at long-term follow-up. Stenting deserves to be considered a safe and effective alternative to CABG in institutions performing large numbers of PCIs.

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Major Determinants for Long-Term (5-year) Outcomes after Coronary Stent Implantation for Unprotected Left Main Disease

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Background: The clinical and angiographic characteristics identifying high-risk subsets of patients with unprotected left main coronary artery (LMCA) disease undergoing percutaneous coronary intervention (PCI) might be critical for optimal management and improving outcomes

Methods and Results: Between 2000 and 2006, a total of 1102 patients with unprotected LMCA disease received PCI with stenting. During long-term follow-up of median 5.2 years, 138 patients died and 171 patients had target-vessel revascularization (TVR). Twenty-six pre-procedural parameters were evaluated by univariate and multivariate Cox regression analysis to identify independent predictors of all-cause mortality, composite outcome of death, Q-wave myocardial (MI) infarction or stroke, and TVR. Independent predictors of all cause of mortality and composite outcome of death, Q-wave MI or stroke were old age, peripheral vascular disease, renal failure, extent of diseased vessel. Major predictors of TVR were old age, distal LMCA involvement, and right coronary artery disease (Table).

TABLE 1. Independent predictors of all cause mortality, Death, Q wave-MI or Stroke, TVR after unprotected percutaneous LMCA revascularization.

Independent predictors of all cause mortality		
Variables	HR(95% CI)	P value
Age ≥ 75	2.53 (1.62 to 3.97)	<0.01
Peripheral vascular disease	2.98 (1.16 to 7.67)	0.02
Renal failure	5.19 (2.83 to 9.51)	0.00
Extent of diseased vessel		
Left main only	1.0	
Left main plus single-vessel disease	1.84 (0.98 to 3.45)	0.06
Left main plus double-vessel disease	1.22 (0.62 to 2.40)	0.56
Left main plus triple-vessel disease	2.84 (1.22 to 6.64)	0.02
Independent predictors of Death, Q wave-MI or Stroke		
Variables	HR(95% CI)	P value
Age ≥ 75	2.73 (1.78 to 4.18)	<0.01
Peripheral vascular disease	2.88 (1.11 to 7.47)	0.03
Renal failure	5.30 (2.97 to 9.50)	0.00
Extent of diseased vessel		
Left main only	1.0	
Left main plus single-vessel disease	1.69 (0.90 to 3.17)	0.10
Left main plus double-vessel disease	1.13 (0.59 to 2.16)	0.71
Left main plus triple-vessel disease	2.11 (1.16 to 3.83)	0.01
Independent predictors of TVR		
Variables	HR(95% CI)	P value
Age ≥ 75	0.50 (0.27 to 0.90)	0.02
Left main distal bifurcation disease	1.56 (1.14 to 2.12)	0.005
Right coronary artery disease	1.36 (0.99 to 1.86)	0.054

Conclusions: Several clinical and angiographic characteristics were identified as important predictors for long-term adverse outcomes after stenting in patients with unprotected LMCA disease. Considering these factors may be helpful to guide optimal treatment strategy for these, "high-risk" patients.

TCT-149

Bifurcation Stenting With a New Generation DES: One Year Clinical Outcomes In 671 Patients

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Aims: Lesions at coronary bifurcation represent a challenging area in interventional cardiology with higher rate of adverse events. Search for most optimal treatment is still ongoing and our aim was to investigate safety and performance of Nobori, a new generation DES in this lesions subset. Nobori stent might offer an efficient treatment thanks to its easy access to side branches.

Methods: In total 671 patients were enrolled in NOBORI Bifurcation substudy in the frame of large NOBORI 2 study. The primary endpoint of the study is target lesion failure (TLF) defined as cardiac death, myocardial infarction target vessel related (MI) and target lesion revascularization (TLR) at 12 months post-procedure. Data are entered electronically with an extensive monitoring (100% on-line and 30% on-site). An independent clinical event committee adjudicates all adverse events and an

independent corelab analyzes baseline and adverse events angiograms.

Results: There were significantly more male patients in bifurcation group (83% vs. 77%; $p < 0.001$). Number of treated lesions and implanted stents per patient in bifurcation group were higher, lesions were significantly more complex (91% vs. 67% types B2 and C lesions; $p < 0.001$), more frequently in the left coronary system and at ostium (20% vs. 9%; $p < 0.001$) less often occluded (7% vs. 11%; $p = 0.004$) longer and with lower MLD (2.45 ± 0.45 mm vs. 2.51 ± 0.47 mm; $p < 0.001$) post-procedure. Majority of the bifurcation lesions were classified as 1.1.1. (36%) followed by 0.1.0 (18%) and 1.1.0 (15%) according to Medina classification. At 1 year 97% of the patients were available for follow-up and TLF was 4.8% in bifurcation and 3.3% in non-bifurcation group ($p = 0.08$). In bifurcation group, 4 patients died (0.6%), 15 patients suffered MI (2.2%) and 15 patients underwent TLR (2.2%). In non-bifurcation group, 27 patients died (1.1%), 31 had an MI (1.3%) and 39 patients TLR (1.6%). Stent thrombosis rate was similar in the two groups (0.9% in bifurcation and 0.5% in non bifurcation; $p = 0.28$).

Conclusion: Good procedural success and low rates of death, MI, TLR and stent thrombosis at 1 year indicate that Nobori DES is safe and effective for bifurcation treatment. The large cell opening of this stent, with enhanced access to side branch, the biodegradable polymer and the abluminal coating might have contributed to good outcome even in this very complex patient subset.

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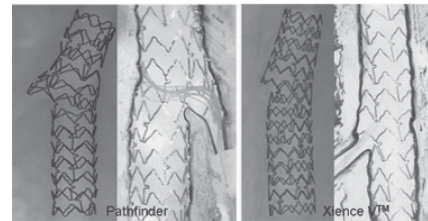
Evaluation Of An Everolimus Eluting Dedicated Bifurcation Stent In Comparison With Xience VTM Coronary Stent In A Porcine Coronary Model

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Purpose: Stenting of coronary bifurcation lesions often results in complications like dissections, leading to an increased rate of restenosis, in particular at the side-branch (SB) ostium. This is thought to be due to insufficient support of the side-branch by the stent structure. We studied a newly developed dedicated bifurcation stent (Pathfinder) and compared it to the standard clinically available stent (XIENCE VTM) in a porcine model of coronary bifurcation stenting.

Methods: Stents were implanted in LAD/diagonal and LCX/marginal bifurcations with a stent to artery ratio of 1.1 under guidance of 2D and 3D QCA. Each animal received Clopidogrel and ASA throughout the follow-up period (acute, $n = 9$ and 7 days, $n = 7$). Animals received both stent types and all completed the protocol. We assessed the implantation efficacy of the stents by high resolution imaging techniques in vivo (OCT) and ex vivo (microCT), followed by dedicated histology assessment (en-bloc Toluidine blue stained longitudinal and cross-sectional slides of the bifurcation).

Results: Pathfinder implantation needed less contrast use than XIENCE VTM, (26 ± 19 ml vs 63 ± 36 ml, $p = 0.024$). Both stents were uniformly expanded in the main vessel (MB). In all cases (left figures: microCT, Pathfinder extended into the SB) Pathfinder showed better SB ostium coverage than the XIENCE VTM. With the small sample size ($N = 4-7$), there were no significant differences between Pathfinder and XIENCE in acute ($11 \pm 23\%$ of the struts vs $30 \pm 38\%$, $p = 0.3$) or chronic thrombus formation, ($40 \pm 34\%$ vs $49 \pm 22\%$, $p = 0.6$), malapposition ($23 \pm 24\%$ vs $4 \pm 8\%$, $p = 0.1$) and endothelial coverage of the MB at 7 days (both 43%).



Conclusions: Pathfinder supports the SB ostium, as evidenced by a preserved diameter on QCA and microCT. It showed similar thrombus formation and strut apposition as compared to XIENCE VTM.

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Very Long-term (>6 Years) Clinical Outcomes Following Drug-eluting Stent Implantation For Unprotected Left Main Coronary Artery Disease

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Background: According to current guidelines, percutaneous treatment of unprotected left main coronary artery (ULMCA) has a Class IIb indication. Multicenter registry data of ULMCA treatment with DES implantation have reported encouraging results up to 3 years of follow-up.

Methods: All consecutive patients who underwent elective implantation of either sirolimus- (SES) or paclitaxel-eluting stent (PES) for de novo ULMCA lesions between March 2002 and May 2005 were analyzed with the aim to report very long-term clinical outcomes.

Results: A total of 149 pts were treated: 68 (45.6%) with PES and 81 (54.4%) with SES implantation. Distal left main disease was found in 113 (75.8%) patients. High mortality risk scores (Euroscore > 6) were present in 47 (31.5%) while complex angiographic characteristics (SYNTAX SCORE ≥ 33) were found in 43 patients (29%). A double stent technique was performed in 108 (72.4%) patients with the 'Crush' technique most utilized in 38% of cases. Periprocedural MI rate was 8.1% while no Q wave MI, death or urgent CABG occurred during hospitalization. Angiographic follow-up was performed in 128 patients (85.9%). At a median follow-up of 6 years (IQR 5.1-6.8), 27 (18%) patients died. Among them 13 (9%) were cardiac deaths. Of these, 8 could be considered as possible late stent thrombosis (ST). One pt had a definite late ST at 3.9 months while on double anti-platelet therapy. TVR occurred in 42 (28%) patients (34 re-PCI and 8 CABG) and TLR in 22 (15%) of whom 21 (14.6%) were in pts treated for distal LMCA stenosis.

At long-term follow-up (>6 years), freedom from death, MI and cerebrovascular events was 78.2%.

Conclusions: Treatment of ULMCA stenosis with DES appears associated with favorable clinical outcomes maintained at very long term (>6 years) clinical follow-up.